PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Case 21422 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/10495	International filing date *(day/month/year)* 22.09.2003	Priority date *(day/month/year)* 27.09.2002
International Patent Classification (IPC) or both national classification and IPC C12P17/04		
Applicant DSM IP ASSETS B.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20.03.2004	31.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Devijver, K Telephone No. +31 70 340-4124

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/10495

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-4 received on 03.08.2004 with letter of 02.08.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-4
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-4
Industrial applicability (IA)	Yes:	Claims	1-4
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. CITATIONS

Reference is made to the following documents:

D1: WO 03 104445 A (ROCHE VITAMINS AG ;SUGISAWA TERUHIDE (JP); MIYAZAKI TARO (JP); HOS) 18 December 2003 (2003-12-18)
D2: WO 03 089634 A (ROCHE VITAMINS AG ;SUGISAWA TERUHIDE (CH); MIYAZAKI TARO (JP); HOS) 30 October 2003 (2003-10-30)
D3: EP-A-0 922 759 (HOFFMANN LA ROCHE) 16 June 1999 (1999-06-16) cited in the application

2. NOVELTY (Art. 33(2) PCT)

2.1 The present application does not satisfy the criterion set forth in Article 33(2) PCT, because the subject-matter of claims 1-4 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

2.2 Document D3 (cf. the whole document) discloses the same aldehyde (L-sorbosone) dehydrogenase as the one described in the present application. D3 (cf. page 2 line 56 and claims 1-14) also discloses a process comprising contacting L-sorbosone with said purified dehydrogenase in the presence of an electron acceptor. In carrying out the teaching of said prior art document, the skilled person would inevitably arrive at a result falling within the terms of the claim, namely producing vitamin C, because the starting products and the process are identical (PCT Guidelines, 12.04). Hence, claims 1-4 lack novelty in the light of D3.

2.3 The applicant has not been able to show, e.g. by appropriate comparison tests, that differences do exist with between the presently claimed process and the prior art process, e.g. with respect to the parameters of the process.

3. INVENTIVE STEP (Art. 33(3) PCT)

3.1 Even disregarding the above made novelty objection, the present application does not satisfy the criterion set forth in Article 33(3) PCT, because the subject-matter of claims 1-4 does not involve an inventive step in the sense of Article 33(3) PCT.

3.2 Document D3 (cf. the whole document) is considered to represent the most relevant state of the art. Document D3 discloses the same aldehyde (L-sorbosone) dehydrogenase as the one described in the present application. D3 (cf. page 2 line 56 and claims 1-14) also discloses a process for producing 2-keto-L-gulonic acid (2-KGA) comprising contacting L-sorbosone with said purified dehydrogenase in the presence of an electron acceptor. The subject-matter of claims 1-4 differs in that vitamin C is produced by carrying out said process. Hence, the problem to be solved by the present application may be regarded as providing a process for producing vitamin C. The proposed solution is the process of claims 1-4.

3.3 However, the examiner has well-founded reasons for believing that the person skilled in the art would be unable, on the basis of the information given in the application as filed, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis. These reasons are supported by a published document, namely D3, which shows that when carrying out the process of claims 1-4, 2-KGA is produced instead of vitamin C (PCT Guidelines, 5.44). Consequently, the person skilled in the art is unable to carry out the entire scope of the claimed invention (PCT Guidelines, 5.48). Since a prerequisite for acknowledging an inventive step is the fact that the problem should be solved over the whole scope of the claims, present claims 1-4 cannot be considered to involve an inventive step in the sense of Article 33(3) PCT.

4. FURTHER REMARKS

4.1 In the light of the above paragraphs 2.3 and 3.3, it appears that an essential technical feature is missing in the claims to provide a process for producing vitamin C (Art. 6 PCT taken in combination with Rule 6.3(b) PCT).

4.2 Claim 1 relates to a product, namely a purified L-sorbosone dehydrogenase,

defined by its parameters. Said claim would be more clear (Art. 6 PCT) if the subject-matter of claim 2, namely that the L-sorbosone dehydrogenase is derivable from the strain Gluconobacter oxydans DSM No. 4025 (FERM BP-3812) or mutants thereof which have the same dehydrogenase, would be incorporated in claim 1. Moreover, the application only provides sufficient support (Art. 6 PCT) and sufficient disclosure (Art. 5 PCT) for the L-sorbosone dehydrogenase derivable from the strain Gluconobacter oxydans DSM No. 4025 (FERM BP-3812) or mutants thereof which have the same dehydrogenase. Hence, in order for claim 1 to comply with Articles 5 and 6 PCT, said claim requires amendment.

4.3 In order for claim 2 to comply with Articles 5 and 6 PCT, the expression "a microorganism belonging to the genus Gluconobacter or mutants thereof" should be functionally limited to those microorganisms and mutants which have the same L-sorbosone dehydrogenase as Gluconobacter oxydans DSM No. 4025 (FERM BP-3812). The expression "having the identifying characteristics of G. oxydans DSM No. 4025 (FERM BP-3812)" is not clear and hence does not unambiguously functionally limit the aforementioned microorganisms and mutants.

4.4 Certain published documents (Rule 70.10)

	Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
D1	WO03104445	18-12-2003	30-05-2003	06-06-2002
D2	WO03089634	30-10-2003	14-04-2003	22-04-2002
				06-06-2002

D1 and D2 claim an earlier priority than the present application and will therefore become of relevance for the novelty of the claimed subject-matter during regional phase examination.